

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kurt-Reiner Geiss Confirmation No. 4213
Serial No.: 10/665,394 Examiner: Snigdha Maewall
Filed: September 17, 2003 Art Unit: 1612
For: **FOOD PRODUCT FOR IMPROVING COGNITIVE FUNCTIONAL CAPACITY**

**DECLARATION OF DR. KURT-REINER GEISS
UNDER 37 C.F.R. § 1.132**

I, Kurt-Reiner Geiss, do declare as follows:

1. I am the inventor of the subject matter in U.S. Patent Application No. 10/665,394 which was filed on September 17, 2003.
2. I received my medical degree on May 10, 1983 and my Ph.D. on February 11, 1987, both from the university hospital in Frankfurt, Germany.
3. Currently, I am the medical director of the research institute ISME, Mörfelden/Frankfurt, Germany.
4. Since 1992 I have been specializing in clinical studies (human intervention studies) which examine the effects of nutrient ingredients in humans.
5. I have reviewed the Office Action from the United States Patent and Trademark Office (“USPTO”) dated March 12, 2009. I have also reviewed the prior art cited in the Office Action. In particular, I have reviewed **Buchholz et al.** (U.S. Patent No. 6,514,973 B1), and **Lang et al.** (U.S. Patent Application Publication 2003/0161861 A1).
6. I am submitting this Declaration first, to support the general finding that the claimed food/food bar, which includes a combination of phosphatidyl serine and carbohydrates, provides measurable improvements in cognitive functional capacity upon consumption of the food/food bar and second, to support the particular finding of an unexpected synergistic effect of

the combination of phosphatidyl serine and simple carbohydrates to improve cognitive performance, such as increasing memory, concentration, and attentiveness in the consumer of the food/food bar.

7. At my direction and under my supervision, I had a clinical trial conducted wherein the effect of a combination of phosphatidyl serine and carbohydrates on concentration, memory, and attention in middle-aged adults was evaluated. The methods and results of this clinical trial are presented below for consideration by the Examiner.

8. Experimental Example One

Method:

Volunteers were recruited through an advertisement in the Austrian newspaper "Krone Zeitung", looking for volunteers for a clinical study on memory, concentration and attention (attentiveness). 29 volunteers participated in the study. The average age was 59 years. Characteristics of the volunteers can be found below in table 1.

Table 1: Subjects characteristics

| | Age (years) | | Working / Retired | | Total |
|-------|-------------|------|-------------------|---------|-------|
| | < 50 | > 50 | Working | Retired | |
| Men | 4 | 10 | 8 | 6 | 14 |
| Women | 2 | 13 | 6 | 9 | 15 |
| Total | 6 | 23 | 14 | 15 | 29 |

The volunteers were evaluated pre-supplementation and again after 12 weeks of consuming one IQPLUS Brain Bar (containing 200 mg of phosphatidyl serine and 20 g of carbohydrates) per day for the first 2 weeks, followed by half an IQPLUS Brain Bar for the next 10 weeks. After the second evaluation, the volunteers stopped taking the IQPLUS Brain Bar and were re-tested in week 24.

Concentration and attention (attentiveness) were evaluated in a psychometric test by G. Gatterer. The volunteers were tested in time needed to complete a task, amount of correctly recognized symbols, number of mistakes, and mistake rate. Memory and attention were assessed by the reading 4 lines of characters, recollecting lines of characters, and recollecting lines of number test by S. Lehrl.

Result: The combination of phosphatidyl serine and carbohydrates in form of the IQPLUS Brain Bar resulted in improvements in all categories of concentration and attention (results after 12 weeks of IQPLUS Brain Bar consumption in comparison to starting values). Comparison of results after 12-weeks consumption with results after additional 12-week without any further supplementation showed a decline in all categories at week 24. Test results (comparison week 1 and 12, comparison week 12 and 24) can be found below in table 2.

Table 2: Concentration and Attention

| Task | Improved | | Declined | | Unchanged | | Total | |
|--|----------|-----------|----------|-----------|-----------|-----------|----------|-----------|
| | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 |
| Time needed to complete task (Seconds) | 72.4 | 27.6 | 29.6 | 70.4 | 0 | 0 | 100 | 100 |
| Correct recognized Symbols | 27.6 | 18.5 | 27.6 | 44.4 | 44.8 | 37.0 | 100 | 100 |
| Total mistakes | 6.9 | 3.7 | 3.5 | 22.2 | 89.7 | 74.1 | 100 | 100 |
| Mistake rate (percentage) | 10.3 | 7.4 | 3.5 | 25.9 | 86.2 | 66.7 | 100 | 100 |

The combination of phosphatidyl serine and carbohydrates in form of the IQPLUS Brain Bar resulted in improvements in memory and attention (results after 12 weeks of IQPLUS Brain Bar consumption in comparison to starting values). Comparison of results after 12-weeks consumption with results after additional 12-week without any further supplementation showed a decline at week 24. Test results (comparison week 1 and 12, comparison week 12 and 24) can be found below in table 3.

Table 3: Memory and attention

| Task | Improved | | Declined | | Unchanged | | Total | |
|---|----------|-----------|----------|-----------|-----------|-----------|----------|-----------|
| | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 | 1 vs. 12 | 12 vs. 24 |
| Read lines of characters as fast as possible (RE) | 75.8 | 66.7 | 24.2 | 33.3 | 0 | 0 | 100 | 100 |
| Recollect lines of numbers (RN) | 34.5 | 40.7 | 34.5 | 29.6 | 31.0 | 29.6 | 100 | 100 |
| Recollect lines of characters (RC) | 44.8 | 29.6 | 24.1 | 33.3 | 31.0 | 37.0 | 100 | 100 |
| Total (RN+RC) | 58.6 | 44.4 | 27.6 | 37.0 | 13.8 | 18.5 | 100 | 100 |
| C (follows from RE, RN, RC) | 79.3 | 59.3 | 20.7 | 33.3 | 0 | 7.4 | 100 | 100 |

9. At my direction and under my supervision, I had another clinical trial conducted wherein the effect of phosphatidyl serine alone, simple carbohydrates alone, or a combination of phosphatidyl serine and simple carbohydrates on cognitive function, attentiveness, and

concentration were compared. The methods and results of this clinical trial are presented below for consideration by the Examiner.

10. Experimental Example Two

Methods: The golf swing is a complex motion and especially teeing off creates high levels of tension with potential negative effects on cognitive function, attentiveness and concentration, resulting in reduced performance. Golfers with handicaps 19-36 participated in a clinical trial measuring tee-off accuracy. The subjects received a standardized breakfast and were not allowed to train or consume caffeine or any other stimulants. The subjects performed a standardized 10 minute warm-up which did not include practice shots. The 10 minute warm up consisted of a golf-specific eight step warm-up program of one minute each: 1. stationary jumping and running with upper body rotation, 2. upper body rotation and arm lift, 3. back and forth leg weight distribution, 4. upper body rotation simulating swing movement, 5. golf swing with horizontal club, 6. left and right arm one arm swing, 7. left and right arm horizontal swing, 8. golf swing without ball contact, followed by two minutes of golf swings with ball contact. A visual representation of the warm-up is shown below in Figure 1.

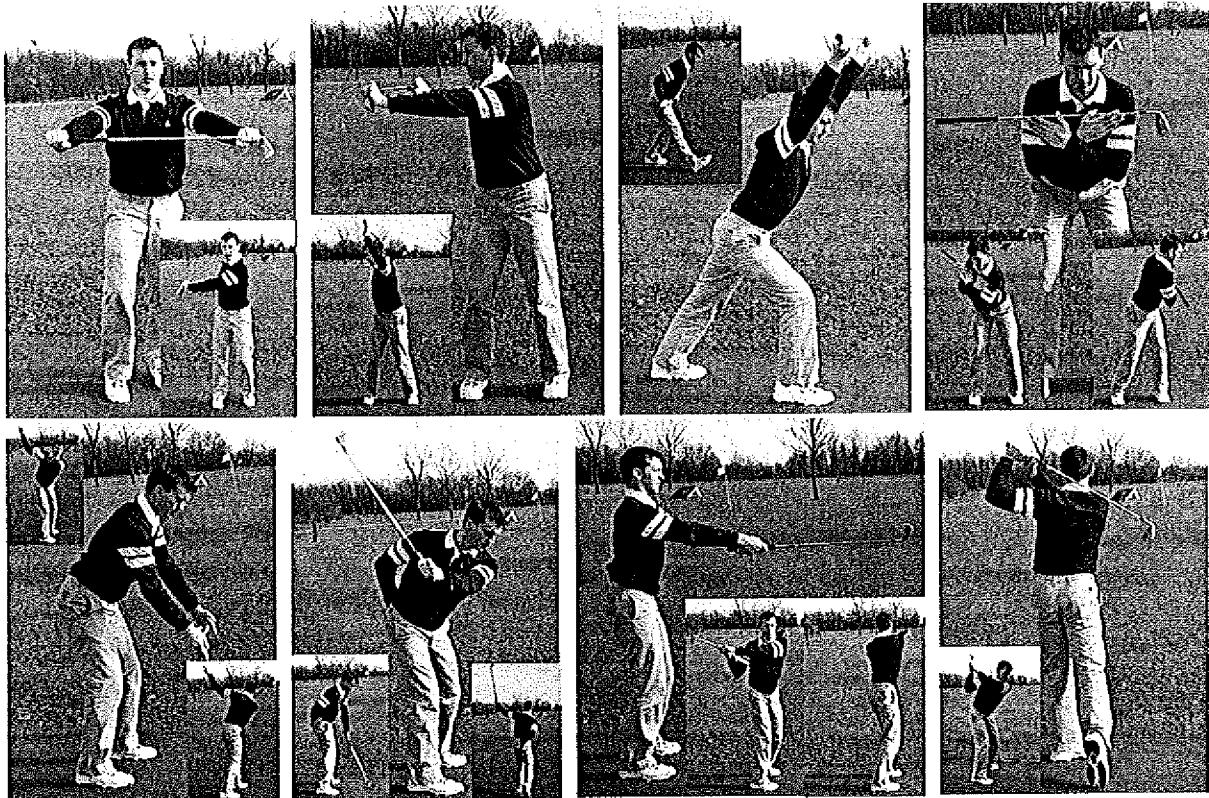


Figure 1: Standardized warm-up.

After the warm up subjects teed-off 20 times in 15-seconds intervals and were asked to hit a target at a distance of 135 meters. The quality of the ball flight was recorded immediately after the ball hit the ground after tee-off. A good ball flight (hit) was defined as "correct flight", "draw" or "fade", whereas all other ball flights were recorded as a miss.

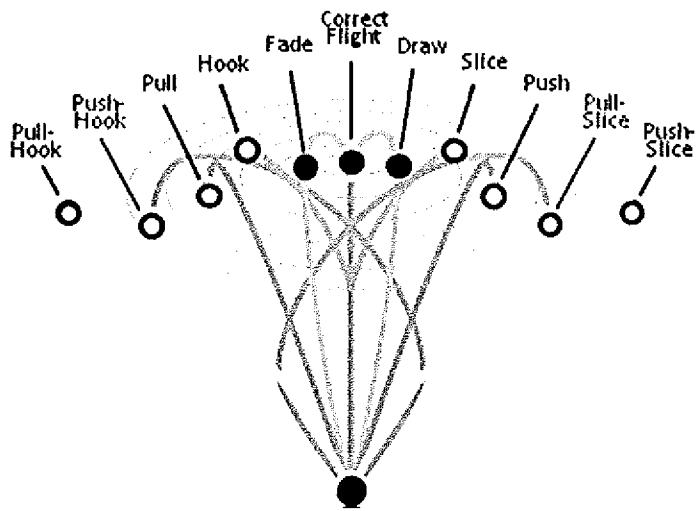


Figure 2: Schematic representation of potential ball flights: correct flight, fade and draw were rated as a hit, all other ball flights were rated as a miss.

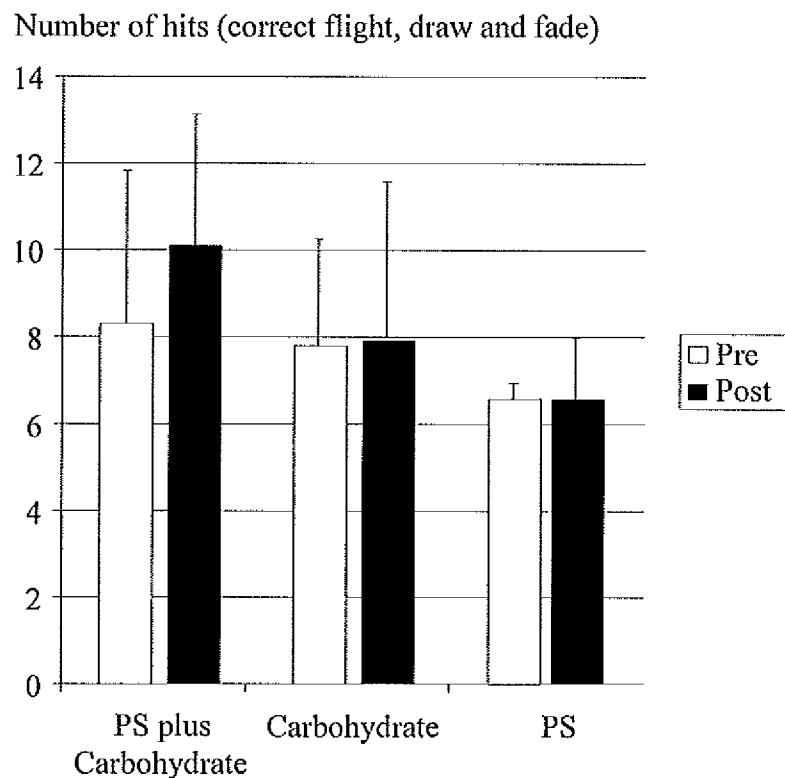
After the first test the subjects consumed a combination of 200mg phosphatidyl serine and 20g of simple carbohydrates (as IQPLUS Golf Bar, n=10) or 20 g of simple carbohydrates (as a nutrition bar, n=10) or 200 mg of phosphatidyl serine (as soft gel capsules, n=2) for 6 weeks. After six weeks the test was repeated and the subjects reported that their individual physical, mental, and golf specific training habits were unchanged during the supplementation phase.

Table 1: Subjects characteristics at pre-test

| | Phosphatidyl serine (200 mg) and Carbohydrate (20 g) | Carbohydrate (20 g) | Phosphatidylserine (200 mg) |
|--------------------|--|---------------------|-----------------------------|
| Number of Subjects | 10 | 10 | 2 |
| Age (years) | 33.1 ± 7.5 | 31.4 ± 4.5 | 39.5 ± 0.5 |
| Bodyweight (kg) | 77.6 ± 7.8 | 84.6 ± 13.2 | 85.0 ± 3.0 |
| Height (cm) | 181.3 ± 8.8 | 183.6 ± 5.0 | 190.0 ± 8.0 |
| Handicap | 26.8 ± 7.5 | 27.8 ± 8.0 | 27.0 ± 4.0 |

Result: The combination of phosphatidyl serine and simple carbohydrates resulted in a significant improvement of good ball flights (plus 22%: mean: pre-test 8.3 +/- 3.5, post-test 10.1 +/- 3.0), whereas simple carbohydrate intake (mean: pre-test 7.8 +/- 2.4, post-test: 7.9 +/- 3.6) or phosphatidyl serine intake (mean: pre-test 6.5 +/- 0.5, post-test: 6.5 +/- 1.5) did not improve performance. The improvement was statistically significant ($p < 0.05$).

Figure 3: Schematic representation of potential ball flights: correct flight, fade and draw were rated as a hit, all other ball flights were rated



This shows a synergistic effect of phosphatidyl serine and simple carbohydrates over the effect of the individual ingredients (phosphatidyl serine or simple carbohydrates).

11. Experimental Example Three

At my direction and under my supervision, I had another clinical trial conducted with golfers using identical conditions as in Experimental Example Two. The subjects ($n=2$) consumed 150mg of phosphatidyl serine and 15g carbohydrates on average per day for a period of eight weeks. This group showed a 14% improvement in good ball flights (pre 6.5; post 7.4; difference 0.9 = 14%).

12. In all three experiments, subjects were instructed to avoid changes in their diets and changes in their physical, mental, and golf-specific training during the study. This is an art-accepted way to exclude interference from nutrients coming from the daily diets of the subjects when interpreting the resulting data.

13. I believe that the results of the first noted clinical trial (Experimental Example One) support the conclusion that the claimed food/food bar, which includes a combination of phosphatidyl serine and carbohydrates, provides measurable improvements in cognitive functional capacity upon consumption of the food/food bar, and further, the results of the second and third noted clinical trials (Experimental Examples Two and Three) support the conclusion that the unexpected synergistic effect of a combination of phosphatidyl serine and simple carbohydrates to improve cognitive performance render the claimed food compositions unobvious in view of the prior art.

14. I note that neither the cited art (Buchholz et al. and Lang et al.) nor any other prior art teaches the addition of simple carbohydrates to phosphatidylserine with the purpose or expectation that both would interact to actively improve cognitive functional capacity, such as increasing memory, concentration, and attentiveness.

15. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing from the application referenced herein

Date: 12.06.09. By: K.R.

Kurt-Reiner Geiss